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GROUP 120

[ERoberts Art Unit 125
930,194 08/02/78
Ulrich Stache]

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THIS IS A COMMUNICATION FROM THE EXAMINER
IN CHARGE OF YOUR APPLICATION.COMMISSIONER OF
PATENTS AND TRADEMARKS

- ☒ This application has been examined.
☐ Responsive to communication filed on _____
☐ This action is made final.

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS ACTION IS SET TO EXPIRE 3 MONTH(S)
_____ DAYS FROM THE DATE OF THIS LETTER.

FAILURE TO RESPOND WITHIN THE PERIOD FOR RESPONSE WILL CAUSE THE APPLICATION TO BECOME ABANDONED.
35 U.S.C. 133

PART I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

1. ☒ Notice of References Cited, Form PTO-892. 2. ☐ Notice of Informal Patent Drawing, PTO-948.
3. ☐ Notice of Informal Patent Application, Form PTO-152 4. ☐

PART II SUMMARY OF ACTION

1. ☒ Claims 1-5 are pending in the application.
Of the above, claims _____ are withdrawn from consideration
2. ☐ Claims _____ have been cancelled.
3. ☐ Claims _____ are allowed.
4. ☒ Claims 1-5 are rejected.
5. ☐ Claims _____ are objected to.
6. ☐ Claims _____ are subject to restriction or election requirement.
7. ☐ The formal drawings filed on _____ are acceptable.
8. ☐ The drawing correction request filed on _____ has been ☐ approved.
☐ disapproved.
9. ☒ Acknowledgement is made of the claim for priority under 35 U.S.C. 119. The certified copy has
☒ been received. ☐ been filed in parent application:
☐ not been received. ☐ serial no. _____ filed on _____
10. ☐ Since this application appears to be in condition for allowance except for formal matters, prosecution as to merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.
11. ☐ Other

Serial No. 930,194

2

Art Unit 125

The claims in the case to be acted upon are 1-5.

Claims 1, 3, 4 and 5 are rejected under 35 USC 103 as being obvious from the disclosure of Stache et al in combination with Ercoli et al. The primary reference discloses 17 α , 21- ortho carbonate derivatives of $\Delta^{1,4}$ - pregnadiene derivatives. Ercoli discloses a process for the preparation of 17-mono esters of 17.21-dihydroxy steroids by subjecting their 17 α . 21-ortho precursor to an acid hydrolysis. Thus for instance if the method shown in Ercoli were applied to the ortho esters of the primary reference, the claimed compounds would be obtained. Hence, the claimed C-17 mono esters, the C-17.21-mixed diesters and the compositions thereof would be obvious to one of ordinary skill in the art with the references of record before him; especially in view of the ^{Chemical} ~~Chemical~~ Abstract Publication which shows the C-17 mono carbonates to be old in the art. With respect to claim 5, it is the Examiner's position that one of ordinary skill in the art, upon contemplating the nature of the claim, in view of his knowledge that closely related steroid compounds have been combined with pharmaceutically acceptable carriers in a manner similar to that here and administered to treat inflammatory conditions, would find adequate suggestion of the subject matter as a whole which is claimed. Obviousness does not demand absolute certainty on the part of one of ordinary skill that the new material will be

Art Unit 125

more or less successful in use than the materials known in the prior art.

Claim 2 is rejected under 35 USC 103 as being obvious from the disclosure of Ercoli et al which shows substantially the same process. See col. 2 lines 3--45 and col. 4 lines 40-52. The mere fact that applicants starting materials differs from that shown by the prior art is of no consequence since an old process does not become patentable anew when applied to closely analogous compounds to obtain expected results.

Claims 1-5 are rejected under 35 USC 112 as not properly defining the alleged invention. The claims are so broad as to read upon subject matter as to which the specification is not enabling and therefore is not in compliance with par. I. In addition, the language in claims 1 and 2 is not clear. The claims are alternative and thus become indefinite. Further, the recitation "hydrolysis" is functional and does not define the process in claim 2 in the manner required by the statute.

Claim 1 is rejected under 35 USC 102 as being fully met in Phillipps et al which discloses the C-17 mono alkyl carbonate esters of betamethasone, The instant claim is not seen to define patentable thereover.

Serial No. 930,194

4

Art Unit 125

The Shapero et al patent is cited to show the present state of the art.

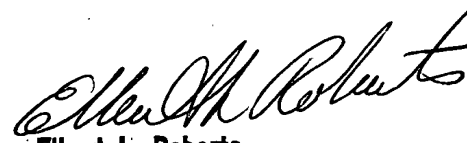
A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS ACTION IS SET TO EXPIRE MONTH(S) FROM THE DATE OF THIS LETTER.

ERoberts/maw

A/C 703

557-2575

04/12/79



Elbert L. Roberts
Primary Examiner
Art Unit 125